DRUG TESTING ADVISORY BOARD

OPEN SESSION

June 5, 2001

Agenda Item: Welcome

MR. STEPHENSON (HHS): Good morning. I'd like to open this meeting by saying thank you to all of you for finding your way here. I'd like to ask before we formally begin with this meeting, who has seen the Federal Register notice advertising the time and location of this meeting?

VOICE: It was published today.

MR. STEPHENSON: I thought it was going to be published tomorrow. We owe you an apology, and it does show how much attention there is paid to this meeting, even when the bureaucracy fails, and we don't get the Federal Register notice out. Our friends and the folks that we work with in these meetings and around these activities seem to find their way. Thank you all for being here today.

DR. BUSH (HHS): I'd like to add to that. Because of such instances of paperwork lag and things that happen in getting this notice published, it's extremely important for you to update and make sure we have your correct email address, because our most able program assistant, Giselle Hersch, knows you all as the family you are to us and the colleagues, she will get you on her family email for the DTAB and you will get these notices and corrections and last minute notices and all that. Email is most important. That's how you will know before the Federal Register notice is published.

MR. STEPHENSON: This is the open session of the Drug Testing Advisory Board meeting. I'd like to make sure that everybody signs in. What Donna had said is very correct. If you can and you want to provide us with your email information, we'll make sure we put you on the list. If you should appear once and want to come back again, we'll challenge your mental acuity, but if you want to come back again in the future and something else happens, then, as Donna said, this would be a good time to get your current email on the list.

We're going to have an opportunity for public comments at the end of this open session. If there is an interest by anyone in making a public comment, please let us know during a break that you have an interest in doing so and we'll set aside equal time for the number of individuals that want to do that.

Agenda Item: HHS Update

DR. BUSH: The first thing I want to start off with is a flyer. It's "Workplace Prevention Research: Substance Abuse Prevention and Early Intervention." CSAP and our Division present

workplace substance abuse prevention, visualizing the future, research, practice, and policy. This is going to be a two-day meeting. The dates are September 6th and 7th at the Hilton Crystal City, Arlington, Virginia. Those of you who have the instant calendar in your head may say: you have a Drug Testing Advisory Board scheduled for September 5th and 6th, and now you tell us the meeting's scheduled for September 6th and 7th. We will have a one-day Drug Testing Advisory Board on September 5th and then we will adjourn and go down to the Hilton Crystal City meeting on September 6th and 7th.

Part of our Division is devoted to the scientific evaluation of best practices in workplace substance abuse prevention, and we have a small grant program that has been ongoing for three years, and a lot has happened. A lot of good things have come out of this research. This is the meeting where it's all going to be discussed and presented.

Since drug testing is an active part of substance abuse prevention in many workplaces, we too shall have one spot on a many and varied agenda. We are going to send out more flyers just to be sure that we continue with the interest generated on this. I'd like everybody to spread the word. I think it's going to be a great meeting.

MR. STEPHENSON: At this point we have a short presentation on an updated web site that we are in the process of developing.

MR. LIPOV (HHS): The URL for this site will be workplace.samhsa.gov. It's still in the development stages. This is the second iteration. The uniqueness of this site will be its comprehensive scope. There are other drug testing and drug-free workplace sites on the web, but this one, we feel, will be the most comprehensive. It's been a little difficult getting to this stage of development due to the comprehensive scope of the site, difficult to develop a lot of material that's organized well and it's relatively easy to navigate.

(Screen)

This is what the home page looks like. We have these different areas at the top and the bottom, the main buttons. As you can see, federal programs, which will provide guidances and regulations; drug-free workplace, which will have material on how to develop drug-free workplace programs; substance abuse, which will have information on prevention and treatment; some links to NIDA on the drugs that are abused, information on that. At the top, resources and tools, we're going to try to put all the documents, publications, videos, electronic debriefings there, and we're going to organize them. On one of the handouts, we provided a classification table for all the resources that are going to go on the web. For now, we're going to just demonstrate what we have in the drug testing button.

(Screen)

As you can see, we know where we're at from the home page. Drug testing is in white, so that tells you you're in the drug testing section. Now, the navigation mechanism. Under urine drug testing, there are no more sub-topics, so that's an open book, but this is a closed book. Here, reason for testing, you have these four areas: pre-employment, reasonable suspicion, treatment follow-up, random testing.

Moving down to specimen collection. That breaks out into urine specimen collection handbook, and you click on that alternative matrix. Well, you've got the current guidelines, which should bring up a pdf file, and I think this is a text file. There's urine specimen collectors

and sites. The major resource for that is actually DATIA that provides a searchable database of collection sites and provides certification and training.

MR. STEPHENSON: I think this gives a pretty good idea of where this is going. The idea is that this will be available on our web site in a better format. We will invite you to come and give us your honest comments, and we'll look at improving it as we go along. The buttons across the bottom that you see are the ways that we have categorized the various areas we want to look at. One area we think is going to be pretty neat that builds on a tool that we use in one of our national clearinghouses is the news headlines area, where we actually will do a daily update from 27 different news sources and we'll monitor and archive all that information. We also have a good search engine which will search inside the site using all of the documents that we have on the site. If you don't know exactly where something might be, you'll be able to get that information from here. We won't necessarily take down other locations where we have information, but this will become an additional location and through this one we'll work hard at setting up new links to other federal agencies and programs and, through the collegial relationships we have with the working groups, continue to post our most current working group products on this site. This is an exciting thing for us and we think that, with the increased interest in workplace programs that has recently been spoken to by the President, that this will be an interesting area for us to work on together. We invite you to become our partners in this and help us make this the best report location that we can.

MR. LIPOV: For those that are used to looking at what we have now on the NCADI site, the list of documents and publications, that will be under this title, and this time, again, they should be organized under regulation and guidance, collection, medical review officer, NLCP program, Drug Testing Advisory Board, future activities, and miscellaneous. It'll be a little easier to find things when looking for the older documents.

MR. STEPHENSON: When do you expect this to be available on a beta environment?

MR. LIPOV: The handout says in the next four to six weeks we expect to go from development - to a beta site, and then we'll do some final testing and then launch. There will still be a couple of areas under construction.

MR. STEPHENSON: We have a couple of additional names that we've been assigned that we'll be able to work with. One is going to be drugfreeworkplace.gov and the other one is .drugtesting.gov. We tried to get workplace.gov, but somebody else said, well, you know, there are a lot of other players in that one. But with those two others, it'll be able to point to our home page when we go live with it. There will be a couple extra links out there. It might be easier for you to remember.

MR. LIPOV: (Screen) Right under urine drug testing, there was a contractor who didn't capture some information we gave him earlier, but recently we told him we wanted frequently asked questions under urine drug testing. That was put together by the staff of DWP. It's a compilation of questions we receive in our Division.

MR. STEPHENSON: This is an interesting site. It's one we have spent a lot of time and effort on, and we're trying to make it not duplicate anything else, but to add and to give some current design qualities to it that will be able to keep up the speed. This is a major undertaking for us and it's taken a while for us to get to this point. We wanted to share it with you.

DR. BUSH: I'd like to give you an update on MDMA and our interest and concern continues on the issue, the incidence and the prevalence and the analytical issues that people see in different arenas, whether it's clinical, whether it's postmortem, whether it's in local bureau of investigations, whether it's driving under the influence through state police programs. A lot of information continues to come in to us, and we have had a couple of laboratories offer to do some method evaluation, immunoassay test kit evaluation, take a look at quantitations or identification of MDMA in specimens below immunoassay cutoffs, concentrations, much in a research mode, to see what might we be missing, how do we have to focus our efforts in detection, and thereby create an effective deterrence mechanism. While I don't have anything specific today, I will ask that anyone who has information, from a state group that might be looking at this from a driving under the influence mode or any other group of specimens that's been analyzed, please let us know. We're very interested in putting together the best kind of compilation of all of this that we can. I'm sure you have my email, dbush@samhsa.gov. You can always email it to me. My phone number is probably in more Federal Register notices than I care to mention, 240-276-2600. That's all for MDMA right now.

MS. MURDOCH (Bensinger, DuPont, Assoc.): Is there any sort of a time line when MDMA may be in the federal panel.

DR. BUSH: We are looking for reagents that can specifically identify this to make the job in the laboratory reasonable and successful in screening and confirming this. We do not have those reagents available right now specifically. That's why we're doing a lot of these evaluations. I do not have a time line.

MR. STEPHENSON: The idea for this is that when we look at what we could do, we could modify the screening cutoff level, stay with existing reagents, and then drive changes in GC/MS to become inclusive. That's going to be very burdensome, it's going to be very costly to get through that confirmation end of the process, and I'm not sure that people really want to do that. What we're working on is to look at assays at the screening end that might be added as an additional reagent to a panel. We have been working with the Food and Drug Administration and are working both with the military and some civilian labs to go through this process. There are some interesting and promising things that are out there and there are certainly going to be more to come as we continue to express interest in this.

There was a recent hearing in the Senate, the Senate Narcotics International Oversight Committee, that looked at this and were very interested in what was happening in terms of screening tests specifically designed to detect MDMA. We've said the same thing there that we're saying here. We want to work on this together. The only way to drive this thing quickly is by reaching out to everybody who has an interest and some experience in it, look collectively at it, and then drive toward a first goal. The first goal isn't going to be the ultimate one, but it will give us something much better than what we have right now. We are committed to doing that. We've got some funds that are set aside yet this year. We hope to bring some of those things to bear yet

by the end of June that will kind of set the stage for some of the things that can happen over the coming months, and then we'll report back to you in September.

DR. BUSH: Part of our concern, Julie, is the analytical burden that including this small molecule, very similar in chemical structure to amphetamines --it's just a plain difficult class of drugs to go in after sensitively and specifically without including everything in the cold preparation aisle in the pharmacy. We want to do it, do it well, focused, and that's what's taking time.

One of your handouts has "Federal Register" across the top of it. This one is a Federal Register notice from May 24th, 2001, published by the Agency for Toxic Substances and Disease Registry. This is an HHS agency. The topic is "Hair Analysis: Exploring State of the Science," panel discussion. It's got a lot of place and purpose and all of this, but if you go down, to make it short and sweet, there are some questions that this group is asking: When is it appropriate to consider hair analysis in assessing human exposures to environmental contaminants? When is it inappropriate to consider hair analysis in assessing human exposures to environmental contaminants? The top of the next page: What data gaps exist that limit the interpretation and use of hair analysis in the assessment of environmental exposures? What research is needed to fill these data gaps? And last, but certainly not least: For what substances do reliable hair analysis methods exist?

We share some similar questions very much in the drugs of abuse mode, and Dr. Barry Sample from our Drug Testing Advisory Board has agreed to attend this meeting in Atlanta. He has agreed to make a presentation on this meeting at the September Advisory Board meeting.

MR. STEPHENSON: Just as a request for information, not necessarily that you have to respond to it, but, Bill Thistle, is this something that you all are planning to attend and participate in?

MR. THISTLE (Psychemedics): We hadn't been because when I read it I didn't think it had anything to do with drugs of abuse.

MR. STEPHENSON: I think the primary thing they're going to be looking at is, believe it or not, I think it's probably going to be nicotine and vitamins. They're going to be looking at some of these things. I'm not sure that it was, but I was just curious whether or not this was one of those meetings that had spiked your attention and that you were participating in.

MR. THISTLE: As I'm sitting here now hearing you talk about it, I guess if it's something that spiked your attention I may rethink the situation, and it looks like Mike will be attending.

MR. STEPHENSON: I didn't mean to put you on the spot, but quite seriously this is what these discussions are for, to help us share the information, make sure we get the best utility out of any opportunity .

MR. CROUCH (DTAB): Do you know what they mean by "environmental contaminants"? Does that mean pollutants?

MR. STEPHENSON: We jumped to the idea that it was going to be arsenic and cadmium.

DR. BUSH: Maybe industrial exposure.

MR. STEPHENSON: Cigarette smoke, stuff like that. That I think is really where they're going.

DR. BUSH: Freedom of Information. Our Division, our Department, works under Freedom of Information availability to the public. There are times when people request things we just don't have. But if we have information related to the request, we provide it under certain guidelines. The point to this about the Freedom of Information Act is that we have received several requests, by unions largely, for a large number of documents, for all laboratories in our national lab certification program, over the last couple of years. The documents that have been requested amount to more than 7,000 sheets of paper and include laboratory inspection critiques, requests for these documents, requests for the cover letters, requests for remedial action, communications between us, national laboratory certification program, and the laboratories.

All of these requests go back for two years. It takes an awful lot of time to prepare these documents because we don't just make photocopies and release these, but according to the rules of us providing information under the Freedom of Information Act, we have the ability to redact or to cover, to essentially make white, cover the area of certain kinds of information, and that's all prescribed in documents from the Department, from the Office of the Secretary.

What's happened in the entirety of SAMHSA at this time, our NLCP-generated laboratory inspection critique, cover letter, remedial action, and correspondence have become the most requested documents in our entire agency. We are going through the extensive time period, the time it takes to actually redact these documents, and because there is such a demand for these we are likely going to scan these into the computer and put them on our web site because so many people are asking for these.

This is likely going to happen before we meet for our September meeting. I think a lot of the interest for these documents has been because of specimen validity testing that has been performed on many specimens under the DOT in a voluntary manner. Laboratories have been performing these tests and I think a lot of people are curious about what labs are doing and maybe they feel the best way is to come to us and ask for these documents. I'm not sure what's going on in the laboratory level. I certainly know what's going on here with the requests for our paper.

That leads me into a segue here for a notice that will hopefully shortly be published in the Federal Register. This will be a change, a proposed change to the mandatory guidelines, and this will be concerning specimen validity testing. I will tell you that this Federal Register notice in its final form for publication, as a call for public comment, is at the Office of the Secretary of HHS for his review and signature. It has been cleared by our Office of General Counsel, signed and forwarded to the Office of the Secretary by the SAMHSA Acting Administrator, Dr. Joseph Autry. This Federal Register notice is directed specifically to federal employees and certainly their unions for comment on the issues that we raise about specimen validity testing, and this will be a 60-day comment period. Recall that DOT has already done this for their regulated industry employees.

The second focus of this Federal Register notice is to the labs and it's about the details that will be required on and for specimen validity testing. A couple of the issues that will be included in this Federal Register notice for comment are shared, are common to what DOT has already gotten comments back on and made decisions on and moved forward with in its final rule. These include access to the split specimen or a second aliquot of a single specimen if that

was what was collected for specimen validity testing, for substituted specimens, for those specimens that are identified as adulterated. In fact, this is linked to the DOT rule. We have always said we want to harmonize in these big picture program areas where that is very possible.

Both the Freedom of Information Act requests that we are getting for information and this specimen validity testing notice that is at Office of the Secretary are outgrowths of issues totally around specimen validity testing.

Another thing that has happened is that the national lab certification program has undergone an extensive revamping of the inspection process focused on specimen validity testing and we're asking laboratories to focus attention on non-negative specimens, whether that be substituted, test not performed, or adulterated. Just a non-negative now has taken on a total generalized class and we need to focus on these.

This is what the public is asking for, our attention to these details, and this is what we plan to deliver through these actions that we're taking right now and things that are ongoing.

MR. EVANS (NOTA): What unions are requesting this information, do you recall?

DR. BUSH: Actually, I don't.

MR. STEPHENSON: If you think about it, they're going to be the types of unions that have been involved where tests are administered, probably related to transportation.

DR. BUSH: They are the transportation industry. I don't actually recall, honestly, but they are transportation because that is where the specimen validity testing has been ongoing in a voluntary manner. I mentioned that there was a revised inspection process that was going to be ongoing here to focus on the non-negatives.

We did a little fine-tuning and issued on March 28,2001, a revised inspection and PT program fee schedule, because this is a cost recovery program in many ways for the services provided directly to the labs concerning their testing, their federally regulated testing. We have certainly a portion of our funding in the contract that we have currently with Research Triangle Institute that is federal money that we use for research purposes and development purposes and education purposes. But for the laboratory side of the business, this is the fee schedule for those services.

DR. SAMPLE (DTAB): When do you expect that the Federal Register notice will be published?

MR. STEPHENSON: We have worked hard to get this through the process and the biggest length of time was to make sure that all of the legal issues were properly covered and addressed, not only within HHS but also with DOT. There has been a level of attention to detail and precision by our Office of General Counsel that, once they signed off on it, they actually ran it up the clearance process inside the Department for their legal levels. Then we hand-delivered a copy for signature in our agency and have expedited getting that up to the Department. We have provided shadow copies to key staff at the Secretary's level and are trying to expedite the process of the clearance of it at that level. Remember, there's little risk at this point because this is a publication inviting public comment. The time is going to be on the other end. It's not going to be on this end. We will continue to monitor it and make sure we've got fresh batteries in the

cattle prod to get it through the gate and out into what we need to have for the next stage of this. I'd be surprised if it doesn't happen in the very, very near future.

DR. BUSH: I promise that we will get the word out. Certainly we're going to send copies to the laboratories and the parties that we have here in attendance at our DTAB, even if it has to be an electronic notification through your email address as to exactly where to go in the Federal Register through the GPO access site. We'll get you to there. We will let you know when this happens. One more reason to get your email address correctly to us. We will put it on our web site. We will have it out there ten ways, any way that we can, because we truly invite public comment.

MR. STEPHENSON: One of the things we haven't thought well through ourselves, but we're going to learn through the experience of DOT, is we're going to use the electronic docket process for the public comments, too. As they come in they'll be archived and shared in the environment, you'll be able to see these in an earlier time than otherwise you would have had an opportunity to do so.

DR. BUSH: Also from DOT's learning curve on the hundreds of comments that they got, sometimes what ends up happening when you do this with an electronic docket showing all the comments that have come up, someone reads the comments and then starts commenting on the comments instead of going back to the original document. Please focus comments on the original document.

Agenda Item: DOT Update

MR. EDGELL (DOT): I'd like to announce that I am still the acting director of our office at DOT. Since we met last, DOT does have a Deputy Secretary. Michael Jackson was confirmed and sworn in by the Secretary in May. We have two or three other administrations with nominations that are in the mill, in process. But as of yet we do not have a new Director of the Office of Drug and Alcohol Policy and Compliance.

On April 30th, all six of the DOT agencies involved in the drug and alcohol program issued proposed modifications of their regulations. This was published in the Federal Register and these are proposed in order that their regulations will become consistent with the new Part 40. Five of these are on a 45-day comment period. The sixth, the Coast Guard's, on a 60-day comment period, and we are working to have these rules, comments, incorporated and the rules published before the first of August.

Part 40 is the law of the land, so to speak, and these conforming rules will simply make that clear. An example of a change in a conforming rule is that the rules, for example, instruct on the functions of the substance abuse professional. All of the substance abuse professional requirements now are in Part 40 and so the motor rules will simply address the employers to Part 40 for the substance abuse professional requirements.

Also, a notice that did go out by the Department, and you have it in your packet, it is a notice that accelerates the compliance date on a paragraph in Part 40, paragraph 40.97, which authorizes the HHS labs to initiate the electronic reporting as the only reporting necessary on negative results. We did this in coordination with HHS when we determined that earlier

compliance with this section should be permitted to promote the utilization of the new, yet almost one year old, chain of custody form. That was issued by the Department on the 23rd of May and it simply puts that compliance date on a faster track, accelerates it by approximately two and a half months.

We are in our office working on some technical corrections which will appear as a Federal Register notice. These are rule changes to correct some problematic issues that needed to have rule text changes in Part 40. Some examples: There was some confusion as to when the refresher training for breath alcohol technicians and screening test technicians needed to take place, needed to be accomplished by. We will in some cases make rule changes, and also in some areas to close out what was pointed out to us as some open-ended items. These tech corrections will be published by July 1st, so that there will be a 30-day notice. Also, the tech corrections will address the issue that Donna Bush just mentioned regarding specimen validity testing. Our preamble pointed out that the specimen validity testing required by DOT with an implementation date of August 1, that implementation date was an anticipated implementation date to come after HHS had completed its process in changing the mandatory guidelines and having those issued in proper time for the laboratories to implement them, and then at that time specimen validity testing would become mandatory for all specimens submitted under the DOT program. We will continue to operate as we have been since January 18th with specimen validity testing, that it is authorized, but it is voluntary for participation by laboratories and employers, that there is medical review on the specimen validity testing, that it's done, and the authorization of the use of the split by the employee to reconfirm.

Those are the most important items, and we will track, work closely with HHS in its preparation and release of that change to the mandatory guidelines and issue a new date in the future for the DOT's mandatory specimen validity testing.

There are also some items that are tech corrections and so those are actual changes to Part 40 that you will see by the 1st of June. We are also working on question and answers, items that we feel the rule covers and so therefore a rule change is not necessary, but since we are still receiving questions --an example is a question that we have received quite a number of times from different sources: Does DOT expect to see the employer's name on the chain of custody form? The rule is very explicit saying that the employer's name and address will be on the chain of custody form. DOT will re-emphasize that in a question and answer. That's something that does not require a rule change, but perhaps does require to be re-emphasized.

Those Q’s and A's will be on our website. We have over the last couple months redesigned our web site. It is www.dot.gov/ost/dapc.

We are working on some manuals, a collection manual, a medical review officer manual, and a SAP manual. We hope to have these out and available, but it will not be before the 1st of August. We are also modifying the breath alcohol technician and the screening test technician model courses. There is only one procedural change, but one of the things that we were doing with the model course, since we have required in Part 40 initial training and refresher training, what we're doing in that model course is to combine those two items into one training manual.

DR. WEST (NRC): I think it would be appropriate for me to give a brief update on the current status of 10 CFR Part 26, the NRC's fitness for duty rule. We've all been anxiously waiting to get the final rule out. The current status is as follows. The Commission approved the rule back at the beginning of December of last year, December the 4th to be exact. We have a final rule that's

approved. It's somewhat in limbo, given the fact that we are before the OMB agency relative to obtaining a clearance.

For any of you that are familiar with rulemaking, even if you aren't, before you can actually publish a rule final in the Federal Register it requires that you have to have an OMB clearance. We've prepared that clearance package. It went before OMB and was issued in the Federal Register. It has a similar process, similar to a proposed rule, where it goes out for roughly 30 days for public comment, and that's sort of where the story gets a little rough relative to the fact that we received extensive comments from the industry and as such the clearance itself is still sort on hold and we've been trying to work through these comments that we've received from the industry. As part of that, we've had several meetings with the industry, first just to get some understanding of what the issues were and then trying to develop various paths to resolving those issues. That process is still ongoing.

In the interim, we've started pulling together a Commission paper where we're pulling together all the aspects of the comments we've received and various options for the Commission to consider relative to getting guidance from the Commission on what should be the next step relative to the rule.

Lastly, we had originally a due date of July 15th to have the final rule to our office of the Secretary, which then in turn would have published it in the Federal Register. But given the dialogues we're having with the industry, the staff requested and received an extension from the Commission until November 30th of this year as a target date for having a final rule to our Office of the Secretary.

To pull all this together, it would be fair to say that we do have some issues with the industry. We're trying to work through those. The Commission is going to have to give us the bottom line guidance. We have to get that in the near term. It won't be days. It will certainly be weeks. Then at that point we'll know where we go from here.

I think it's clear we'll eventually get a final rule out. It's just a matter of a schedule and what form it's going to be in. We have some of the similar kinds of issues that DOT mentioned. We have any number of questions and answers. The crux of the impasse with the industry is, when you do get comments, particularly at this somewhat late stage of the rulemaking process, how do you resolve them. It's essentially in two different areas. You either try to resolve them relative to questions and answers or, depending on who has the issue, it might necessitate a rule change. I think that's some of the aspects of what we're dealing with now.

DR. SAMPLE: I had a question regarding the effective date, particularly if there are going to be rule changes. When that final rule is published, what time frame do you anticipate for that, the difference between the publication date of the final rule and these new rules?

DR. WEST: I can't give you a definitive, but I can give you some possibilities and I think that will certainly speak to your question and perhaps your concern. Initially we had another rule as it's written now, the 90-day implementation period; 90 days after the rule would appear in the Federal Register that would be the effective date. That was not one of the major issues of comments we received from the industry through this OMB public comment period. But we've certainly known from public meetings we've had with the industry on the heels of that public comment period that they would opt for a longer implementation period and effective date. I think it's fair to say that from the staff’s perspective that's certainly something that we would find would be reasonable, to make a recommendation at least to the Commission to consider that.

The possibilities would range from 180 days --I think that's the time frame the industry would opt for --and other similar kinds of considerations that we discussed within the staff talking about this issue. It also seems reasonable, and it comes from the industry as well, whatever the effective date would be, to have some consideration of issuing the rule final and parallel at the same time that you would have the guidance document that would be issued. So that's another possibility.

What I mean by that is that you could have some consideration such that, let's say the rule is issued on whatever day it's issued in the Federal Register, but it wouldn't be effective until --if the guidance document wasn't right there, issued at the same time. You could tie the effective date of the rule itself to the issuance of the guidance document.

Those are some of the options, some of the possibilities. I think it's fair to say as well, even though this is not definitive at this point, that certainly doing something in that area to accommodate the concern and the questions and comments we've received in that area is something that the staff would support.

DR. VOGL (HHS): When Ken Edgell mentioned that DOT is revising the collection handbook and the MRO manual, I want to add that we have agreed that there would be one combined HHS/DOT collection handbook and one HHS/DOT MRO manual. For those who have been involved in the program for the last 12 years, you know that there are two different manuals for collection and MRO. We have agreed to establish just one collection handbook and one MRO manual for both programs.

Agenda Item: Alternative Specimen Testing

MR. LoDICO (HHS): I want to thank the industry working groups for their effort in responding to the questions that were left unanswered in draft 3. From the March DTAB meeting, the chairpersons from each of the industry working groups submitted information in response to a series of questions that related specifically to their alternative matrix. Those questions were presented to them because the Board was concerned that there was not sufficient information or there was not a consensus. We did ask them to respond, to convene a meeting among themselves or to have a telephone conference. At the March DTAB meeting, they responded to the questions and presented to the general public their responses to the questions that we submitted to them.

What did the Board do with that information. The following Power Point presentation is a summary of what has happened since the last DTAB meeting. As you recall, in the process map, there were a series of activities to establish the questions, gather the information, and then use the information to make a decision. We are still at the information evaluation stage because we are on draft 3 of the guidelines. We have received wonderful feedback from the industry group on every section concerning collection and interpretation and cutoffs. At this point, the four groups have responded to the questions from draft 3.

(Screen)

What I have done is compiled data and information from the industry working group (IWG). We've summarized consensus and dissenting opinions and we had a May 16, 2001, telephone conference with participating DTAB members. What that meeting effectively formed was a dissemination of the data that has been collected in our office. When information is given to our office, it is with the explicit intent that it is in a confidential manner. But in the case of the

DTAB, it's our intent to share that information with the participating Board members who volunteered to be part of this drafting of the mandatory guidelines. Along with that, we have given the participating Board members the responses by the industry groups. We provided them additional information concerning some of the minutes of the meetings.

I didn't include the individuals who participated in this presentation. Suffice to say that we had six individuals that attended, we had a varied opinion and shared concerns and acceptance of certain points that were discussed during this conference call.

The first one of the elements discussed was cycle 3 of the special PT samples. That was presented by RTI. Dr. John Mitchell was asked to participate in the telephone conference with the sole purpose that he would give a summary of the performance by the laboratories during the cycle 3 PT. I will summarize what the discussion was concerning the special PT set. At the end of my presentation, Dr. Mitchell will give a presentation specifically on cycle 3 and some of the information that was received from that and how it relates to cutoffs and the ability of the participating labs to effectively hit the target.

The other element discussed is the cutoffs. Are the cutoffs for oral fluid and for hair appropriate? Was there sufficient information and science that supported those particular cutoffs? Based on the information we sent out to the members, there are issues around the cutoffs.

The other element was quality control. This is concerning point of collection testing. Again, the concern is frequency of quality control in point of collection testing. Is a positive and a negative each day sufficient? We also looked at other regulations, specifically with NCCLS, is that complementary to how we are approaching POCT?

The next important element we talked about was specimen utility. Again, we are concerned about when is the specimen properly used, is oral fluid an appropriate specimen to be used for pre-employment? Is sweat an appropriate specimen to be used for a reasonable suspicion or return to duty test?

Lastly, sample volume. What is an appropriate volume? In the draft 3 there is a section that states what is an appropriate volume for each of the matrices for testing for screening and for confirmation. We might get a rule that if a sample, especially again if we're going to use urine as the example that we already exist with in terms of the guidelines right now, we clearly state that if you are doing screening you have to have at a minimum 27 mLs of a urine sample to perform the test. Otherwise, if it falls below that, then it's below the volume and it will have to be cancelled.

PT Cycle 3. What we talked about and what Dr. Mitchell explained, we received the results of the PT cycle 3, but it was really Dr. Mitchell's important briefing that explained whether the laboratories met their stated goal, which is to screen the sample and to confirm it.

John explained the results of the data from the combined set of all three cycles. He talked about comparing the alternative matrix testing PT performance with early urine testing PT performance. We feel it's important to look at when the urine program began in '88, there were CV's by the laboratories that were unacceptable, but yet we went forward with the program.

We don't want to put the burden on the new alternative matrix in terms of their performance under these PT cycles. I think John's going to have a bar graph that illustrates and compares the new matrices with the urine testing performance.

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When discussing cutoffs we want to focus on whether the cutoffs are appropriate. What we talked about were based on the performance of the special PT's, did the cutoffs work

appropriately? Then we looked at the responses by the industry working group and their recommendations and compared those recommendations with the performance of the special PT. Then we looked at the minority dissension, and we had the hair testing working group who state that for THC, that screening would be at one picogram per milligram, and for confirmation it would be 0.05 picogram per milligram. There were some minority dissensions saying that particular cutoff was too low.

The next thing was scientific literature that was contrary to draft 3. We have information that says that in certain drafts --in our draft guidelines we look at the metabolite when the scientific literature would state that the target analyte in that specific matrix is probably more suitable to be the parent.

The other concern about cutoffs is neat versus dilute collections for oral fluid. Do we require that all oral fluid collection be done neat as opposed to a dilute collection? Where the collection itself could have a range of volume from 0.8 to 1.4, which one of the collection devices for oral fluids states is the range. Is that an appropriate collection device since we're looking for cutoffs?

The other thing that was really important is how are the screening microplate EIA's properly applied in terms of the screening, and in particular for hair and THC. We have some response from the manufacturer, who is a microplate EIA manufacturer who sent us a letter saying that perhaps the device is improperly used or applied in the context of screening for hair when it was not meant to be. This information was shared with the participating Board members and again we have to understand whether this is acceptable or unacceptable. In the case of that particular concern, were the controls that were applied using that particular technology, where they're saying that the tolerance of plus-minus 25 percent of the cutoff was unrealistic. This was shared with the Board and we had to make decisions on whether it is appropriate or not.

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Is our program a deterrent program or a detection program? This is the heart of the cutoff issue. If we are a deterrent program, then we need to look at cutoffs that are achievable by laboratories that have LOD's that are robust, that have LOQ's that are robust. If we're looking for detection, then we need to look at reducing even the urine cutoff to the LOD level. The focus of the cutoff was where does this program stand, is it a detection program or is it a deterrent program?

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Under quality control, here the question was always concerning point of collection testing. Dr. Bob Willette and Dr. Yale Caplan were the chairpersons for the POCT group. We had a good discussion and minutes were generated by Dr. Willette. When we discussed the issues of the POCT's cutoff at plus or minus 25 percent --after reading the minutes, it ultimately ends up that there was no consensus to the response on the POCT. Even though they acknowledged that was a problem, ultimately they could not come to a conclusion. Some of the members wanted a plus or minus 50 percent, but at the end they said, no, we can achieve plus-minus 25 percent. Reviewing the response, which we asked them to respond in public, after reading it over again the results are that there's still no consensus concerning the open controls plus-minus 25 percent. We're looking at other documents such as the NCCLS document to see what its recommendations are.

The other issue concerning POCT is the frequency of QC testing and that all ties in with the review of the NCCLS QC recommendations for a single use device. It is a concern because

we are looking at quality control and quality assurance. That is one aspect of the alternative matrix that tends to not have a tighter control and we are concerned about that. We want to be as reliable and as accurate as the laboratory-based testing.

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The other major concern is specimen utility. We are looking at how a specimen is to be used, in what manner, what time, how is the collection going to be performed. We were given an opportunity to review some positivity rates, comparing oral fluid versus urine, and these were predominantly a pre-employment type of data. One of the labs has provided us with this information, it compared the positivity rate of a urine from a retail unit such as one of the big retail firms versus an oral fluid collection from a retail environment. The population was essentially the same. The positivity rate based on just the aggregate numbers were surprisingly the same. This makes a case that if you were to collect an oral fluid sample for pre-employment that you would get the same detection time, the same positivity rate, as you would for urine. Again this was presented to the Board, does this make the case? If it doesn't, then why doesn't it make the case?

MR. STEPHENSON: This brings up a very important point about the kind of dialogue that we have openly engaged in for this Board and in these open sessions. What we have chosen to do is to bring you information as it comes to our attention as we're able the add it and validate it, discuss it, and then make recommendations on it. The draft 3, the guidelines that were posted on the web site, are not gospel. They're draft. The comments that have come in are in responses to holes that were in that. This information that's presented here is different than the recommendations that were in our guidelines in draft 3 of the guidelines on oral fluids. What I'm trying to say to this entire group for everybody to hear loud and clear: Don't take this out as marketing gospel and go sell your individual product based on something that's been presented in a draft text here.

This is going to continue to mature and be modified over time. Allow this process to take place and everybody will benefit from it. If you go out and begin to try to sell or divide the market based on what you think is in that, you'll be behind the power curve and it won't be something that we'll be able to support you on maybe the next time we meet.

MR. LoDICO: The point that I'm trying to make is that we are given an opportunity to share information and that information isn't just received by our office, placed in a file, and forgotten about. Our intent is to be able to discuss and to create a discourse among all the participating individuals who are tasked to give the final version of this document. I think one of the things that we have tried to strive for is an openness and an understanding of what the issues are and how best to present it.

Another important issue is the mean detection times for the different drugs in each of the alternative matrices? It goes to the heart of whether it's hair, oral fluid, or sweat. What are the mean detection times for each of the different analytes.

Another issue is have we established the cross-equivalent specimen utility for the different reasons for collecting each type of specimen. When you look at the different matrices and the specimen utility, what is the cross-equivalent reasons. If you have urine used for pre-employment, what is the cross-equivalent specimen that can be used in that arena, since we're looking for them to have similar utility for each of these specimens.

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Here's an issue for specimen volume. What is the minimum quantity of specimen to be collected? That's in subpart P, 2.4. If you ask the question for a sweat patch, what is the minimum size and the length of time that the donor must wear the sweat patch? Does the dimension of that patch have to be uniform? Is it a de facto square centimeter that it has to be? And what is the length of time? How does that impact on it? Do we have to write it in the guidelines, the patch has to be an inch and a half by two inches and it has to be worn exactly two weeks? This will impact the different cutoffs used.

Concerning oral fluid, the discussion has been that there are different manufacturers of oral fluid devices that have different collections. Do we just ask for only neat collection versus dilute collection, and how much do we ask for that collection to be? Is it one mL, is it two mLs? When we asked the industry group to answer that question, effectively we got maybe three or four different collection scenarios because each of the different manufacturers couldn't accommodate one or the other. Do we arbitrarily choose the number that we want?

In the case of specimen volume, we talked about head hair versus hair from other body sites. The hair testing working group specifically said that head hair is the primary specimen to be collected, but in the event that you don't have head hair then you have different other body sites that you can collect from. Yet you have a minority opinion from the hair testing group that says you only use head hair, and if you don't have head hair then you do not do a collection.

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Now that I've presented the discussions that we had at the May telephone conference, what are we doing next? We're going to schedule a meeting in the near future of the participating working DTAB group to review additional new scientific data. This includes another set of attachments that specifically asks and talks about issues that are still unresolved. Once we've done that, we will complete all of the unanswered questions to draft 3. We will go through draft 3 again, look at all those areas, the sections that have not been answered, answer the questions as best we can, and then write the preamble to the mandatory guidelines for the federal workplace drug testing program.

I understand a lot of the members, the chairpersons, are here to expect some sort of divine answers. But frankly, it's a difficult task answering the last key elements of any of those questions. I'll defer to any of the DTAB members to add anything the I might have left out and to try to keep everybody up to date as to where we are going.

MR. STEPHENSON: One of the points to clarify and to amplify what Charlie said at the very beginning, going back to the experience with urine as the only source for our testing activities, going back to the seventies, was when the NLCP first began. There were, as Charlie said, CV's all over the place in the labs. Yes, the program went on and we certainly undertook the activities of developing the standards, but the labs had to meet the standards to be certified.

DR. BUSH: That's correct. That's what we always have to remember. We see where the CV's were for urine in the past back in the eighties and then we see where they are today. We see that we had at the very beginning a requirement for performance plus or minus 20 percent of the expected concentration that we expected to see, plus or minus two standard CV's, and we held to that. Yes, labs were allover the place, but it was those who could perform well and got that reproducibility around that cutoff that was so important. That's how you focus on accuracy and reliability of the answer that you give.

DR. MITCHELL (RTI): I've got all three matrices in the packet that was on the desk that was labeled with "NLCP Pilot PT Program for Alternate Matrices." We're going to start off with hair and then work through oral fluids and then quickly pass through sweat. By that time it will probably be time for sweat. But I'm going to do it a little bit differently this time. Rather than go through each sample in excruciating pain as we've done in the past, we're going to try to do some generalities and then show some charts, at least on the testing from hair and oral fluid.

The first thing, this time with hair we did things quite differently. Before we just sent them some hair and said: Here, test it. Well, this time we sent the hair and we said: We'd like you to test it two different ways. We'd like you to test it unwashed, that is with no preparation or cleansing of the hair that we send you, and then we'd like you to also do it washed.

We have in these tables that will follow two different scenarios, washed and not washed, and we will talk about that a little bit. But before we get to that, table 3, which is kind of at the end of the hair section, probably about 12, 13 pages back, right before oral fluids, gives you the composition of the samples that we sent out. Things that we can see is that we had a combination --there are only two drug types, mainly two drug types that were sent, that is hair strands containing THCA, the metabolite from THC, and then hair strands which contained cocaine and some of the other compounds resulting from cocaine use, benzoylecgonine and coca ethylene.

The hairs varied. We had hair samples from drug users, 1, 2, and 3, 149, 150, 153. Six samples in the cocaine family which were from drug users. There are some interesting things associated with that. We'll talk about them a little bit.

We tried to cover a large range because there have been some changes in recommendations of cutoffs and things of this nature within the hair group. But we tried to cover a wide span and utilizing ten samples each in order to do this.

Let's go to Table 1 and very briefly, which is on two pages, actually three pages --the explanation is on the third page --which is the initial test data. What we see is that with marijuana or detecting marijuana, six of the laboratories were doing initial tests for marijuana. When we get to --actually, we had seven, but that lab did not tell us that it had switched and was now doing marijuana, so it didn't get all of the samples that would have contained marijuana. Also, we have a total of nine labs that are doing the initial tests for cocaine and its metabolites.

QUESTION: "XXX" means?

DR. MITCHELL: "XXX" means that the test wasn't conducted in that case. The red I believe, as you see on the third --I have to look at this very quickly --the black X's indicate that the test was not performed by the laboratory, but was available. For some reason it was not performed. The red X means that the test was not available at the lab at all.

VOICE: I don't have black and red.

DR. MITCHELL: I know you don't, but you can see it up here. I couldn't afford to make color copies and have 50 of them.

DR. SAMPLE: Can I assume then that no X's and a blank means the lab performed that test, but they did not have a positive result?

DR. MITCHELL: That is correct. If you see a blank, that means that the test is performed, but it was negative. A couple of things that we can see is that with hair we do have what appears to be some false positives in the initial test even though we have not spiked drugs in them. Now, the thing you've got to remember is that in some of these hair samples that we have we do not have an accurate history on them. The person may have been taking some other type of compound to give an amphetamine positive on the initial test.

There are compounds that we know --the phenethylamines will do it, amphetamines. We know that there are some compounds that are taken over the counter that can cause a positive, at least in urine, with PCP. Not knowing the total history that each of the individuals took, medicines that were taken, it's very difficult to predict whether or not that is a true false indication or not of the presence of the drug.

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You can look through this yourself and you can see that it's very difficult to make much of this because you don't know what the values of the drug are at this point in time. But what it does indicate is that the labs are, in looking at it in an overview, that when the drugs are there they appear to be able to detect the drug if it's at or above the cutoffs. That's a general statement about the immunoassays that are currently being used.

Let's go to table 2A and we'll just look at the first page, because what I want to explain is what the table is. We're not going to spend a lot of time on it. 2A is the results that were obtained on hair that wasn't washed at the laboratory, but was tested, but we did not have any directed assay. By directed, that means that if the lab screened it negative and there was analyte there we didn't tell the lab that we wanted them to do a confirmation test, and if the laboratory was not doing a screening test we did not go at this point in time and direct them. The reason that I did this is that in the past when you look at the tables that we'll be looking at a little bit later you'll see a lot of values and it's difficult to comprehend from that that only part of those values would have resulted from a test conducted as a result of an initial test positive. This is just a way of showing that many of the values that we get in this testing phase is directed, either because it's below the cutoff or because it screened negative at that particular laboratory.

MR. CROUCH: For sample 149, six labs screened it positive and four confirmed it positive. Is that correct?

DR. MITCHELL: That's correct. But you'll also notice that there were only four labs that conducted the test for confirmation. That is because we have X's here. There was only one lab that only tested it washed, so there were actually five labs in the system of all these that conducted the test of marijuana by confirmation.

MR. CROUCH: But six screened it positive.

DR. MITCHELL: That's correct. That means there was at least one lab that's doing screening only. The marijuana metabolites appear to be the hardest, as we might well imagine. We'll talk about that a little bit later, but it is one of the hardest metabolites, especially in the hair, where the concentration, you're talking about one picogram or less. With the cutoffs at one picogram for the screening and the cutoff for the confirmation is 0.1 picogram per milligram.

DR. BUSH: I'm focusing again on specimen 149. We have the red X. The red X means?

DR. MITCHELL: I have to go back to it every time. They were not available at the laboratories.

DR. BUSH: There was no screening test available at the laboratory.

DR. MITCHELL: Right.

MR. STEPHENSON: Is that what is meant, John, the specimen wasn't available?

DR. MITCHELL: No, the test is not available at that laboratory. In other words, they do not do confirmatory testing for the marijuana metabolite. You can see here (indicating), lab E, which is the one that only conducted confirmatory testing on the washed samples.

DR. SAMPLE: And likewise, lab A apparently doesn't do confirmation testing for marijuana.

DR. MITCHELL: That's right, lab A does not do confirmation testing for marijuana. This brings out some things that we haven't been able to see in the past because of the broad expanse of the data. Labs K and M, we just got some data in from them and that's not included in here at this point in time. We just got it right as I was doing these tables and I was not able to incorporate it.

DR. VOGL: When you said cycle 3, how long did it take on an average to actually get the results back from the laboratories?

DR. MITCHELL: I don't have that information. It was a while. But you remember, there was a lot going on at that point in time because some of the laboratories here are also certified laboratories in the urine system and they have their April cycles coming up and things like that. There was a lot going on at that point in time. We do have that data and I can get that, but I haven't followed it.

DR. WELCH (DTAB): When the name of the drug is listed in the continuation column does that mean it's a qualitative confirmation, so there was no value, no level determined?

DR. MITCHELL: This (indicating)?

DR. WELCH: No, under lab.

DR. MITCHELL: That means that we ended up directing the result, and we'll see that later in tables C and D.

DR. WELCH: That's why on specimen 159 where zero out of nine labs screened it positive, it looks like they all tried to confirm it?

DR. MITCHELL: Right, and they will be directed for that.

MR. BLEVIN (ANSYS Tech): I'm sorry, I thought you said this slide had no directed assay.

DR. MITCHELL: It has no results from directed assays. We'll get those over in 2C and 2D.

DR. SAMPLE: So that's how they link together.

DR. MITCHELL: Right, that's how they link together.

DR. SAMPLE: At 2A it says that, for instance in specimen 150, lab C was directed to test for THC, but you have to then go to table 2C for lab C, specimen 150, to determine whether or not they identified the drug and, if so, in what concentration.

DR. MITCHELL: That's correct. The same thing with table 2B. Table 2B will be related to table 2B. It's the same thing. This is for the washed. Some of the laboratories did do it both ways and you can see the results from that, especially with the marijuana. We had the washed and unwashed.

Let's go to table 2C very briefly. It's just a couple little things I want to point out.

MR. BLEVINS: Can I ask, was there any difference overall between the washed and the unwashed?

DR. MITCHELL: We'll hit that in just a minute. That's the part that's easier to see than this stuff and that will kind of break this up between the oral fluids and the hair. I do have that.

2C is the not washed results. Look at your means and standard deviations for those. You can see the standard deviations range anywhere from about 33 percent up in the marijuana. We may have had a 20 percent in there. But for the most part they're fairly high for marijuana.

When we get to cocaine, the values can be fairly high also. If you look down here -- excuse me --fairly high. I just want to point that out and then we'll talk about it some more a little bit later. I'm not going to go through all of this. I'm just giving you some general things to look at when you have time to peruse through this data.

It didn't appear that the washed --and that was one of the things I was wondering, whether it was going to do anything for the CV's, that is reducing the CV's. It did appear to drop it some. That is, the standard deviations did drop some.

MR. CROUCH: It also appears that, like sample 154 and 155, if I'm reading this right, are four to five hairs, right?

DR. MITCHELL: Right.

MR. CROUCH: There's not really very much difference between the washed and unwashed concentration.

DR. MITCHELL: That's right. We'll be looking at that. I've got some graphs I'm going to show you in just a minute, Denny, that will compare that where we have sufficient samples to look at the means. There was, at least there appeared to be, some summing. The standard deviations did appear to narrow some with the washing when we allowed washing the samples, based upon the data that we had.

Now, getting to the meat of it, let's look at the cocaine results for comparison of washed and unwashed. The only thing we do as far as cleaning hair is that we put it into water when we get it and stir it, mainly to homogenize the hair. That's the only treatment that we've done to this hair other than, if we spike it, we spike it by the process that we've developed to spike drug into the hair. But for the user's hair, it's only been washed with water and that's distilled water, to try to get rid of any soluble salts from sweat or things like that that are on the outside. So it's not totally like a hair that would be received at a laboratory, where it hasn't gone through that process. As you can see, the values for the samples with cocaine are fairly close between the washed and unwashed, and I'm not sure --I haven't run the statistics on it to tell if one is significantly different from the other at this point in time. 162, we notice that the cocaine in the washed is greater than that in the unwashed, and we'll talk about that a little bit later, even at that level. And the same thing on 166, we see that. Only in those cases do I think we might have a chance that there would be any significance, but since the SD's are so wide, I doubt that there is any statistical significance.

DR. SAMPLE: Some of these are spiked, correct?

DR. MITCHELL: Some are spiked. Remember, 159 is a user. 161 is a user. 162 is from a user. 164, 166, and 168.

MR. CROUCH: What that says is that there's really not very much quantitative difference between the washed and unwashed in spikes.

DR. MITCHELL: That's what it appears.

MR. CROUCH: It's saying the wash is not effective? The wash is not effective for removing drug off the hair.

DR. MITCHELL: What it says is we have a fairly stable spike process that can undergo the washing routines and still give us a PT sample that was viable.

MR. THISTLE: Wasn't that the intent?

DR. MITCHELL: That was the intent.

MR. THISTLE: That was the intent, to create a spike sample that you wouldn't wash off the drug.

DR. MITCHELL: And it's gone through a lot of processing in order to make sure that that happens. We're not trying to draw any conclusions right now on this.

MR. THISTLE: Denny was.

MR. CROUCH: I was just trying to figure out.

DR. MITCHELL: Let's look at benzoylecgonine. We can see that there are some differences

between the not washed and the washed.

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Not real sure why this occurred, unless it is removing BZE from the hair in some of the washing process. But we'll have to look very carefully to see if this is statistically different. The interesting one is this one (indicating). Remember, it was higher with the cocaine on the washed versus the non-washed, and that's from a user. At this time with the BZE, it's extremely elevated.

It's an interesting thing that we're going to have to look at. Scientifically it's interesting; how's that. It may not be to some people, but from a scientific standpoint you're saying, if washing removes it from the hair, how did it go up? I'm not sure, unless in the washing process in this case we're generating in this particular sample, we're generating benzoylecgonine.

DR. SAMPLE: You did say the cocaine also went up in the sample.

DR. MITCHELL: It went up slightly, if I remember. You can see, there it is.

DR. SAMPLE: Are you going to provide Board members with the bar charts?

DR. MITCHELL: Of course.

MR. STEPHENSON: 162, was user hair. It was a drug user hair?

DR. MITCHELL: It was a drug user hair, yes.

MR. LoDICO: Can you convert cocaine to benzoylecgonine in the washing?

DR. MITCHELL: Sure. We know --here's something that we do know. In some of the preliminary stuff that we've done on spiking, we know that there is a small amount that's generated in our spiking process. That is, there is benzoylecgonine generated, small amounts, from the cocaine if we just use cocaine in the spiking process.

We saw earlier, if you'll remember, in the first few cycles there was a great disparity between benzoylecgonine concentrations that were determined by the various labs and we thought that this was conversion of the cocaine in those samples to benzoylecgonine. Most of the laboratories now have processes where they monitor the amount of benzoylecgonine, if any, that they are producing during the extraction, washing extraction process. So they monitor that.

In fact, I think there was a couple labs early on that converted all the cocaine, I think, to benzoylecgonine and I made the comment on cycle 2 it looked like they had begun controlling that process.

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We see the same type of thing from marijuana. There are small differences between the washed and unwashed. But there are some small differences, but I doubt that they're significant considering the size of the standard deviations.

I would encourage you to look through the data that we have presented and draw your own conclusions, rather than us try to stand here and go through each sample and draw

conclusions, because it's a lot of data and it takes a lot of cross-referencing in order to understand it and to make appropriate conclusions.

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The next one is the oral fluids, which is five tables. Let's talk about what we did with oral fluids this time because it gets more complicated as we go along. With the oral fluid, we gave the laboratories twice as much of each of the samples and we said: Here's what we'd like you to do. We'd like you to test each sample as a neat sample, just take the fluid and analyze it. But we'd also like you to take your device that you plan to use as an oral fluid testing, continuation lab or testing lab, we'd like you to take, if you're using the device, pipette the amount of oral fluid that that device is supposed to absorb, pipette it onto it and then proceed as if it was a real sample.

We've got two pieces of data here again. Then after we kind of go through these tables, then we'll look at some of the comparisons and see how they do by analyte.

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Screening. What we'll see in the screening is generally the labs, the initial tests that they are using are able to detect the samples whenever they're above confirmatory --I mean, above the screening level that's been set. I'll just use that as a general thing.

QUESTION: Do you have the spiked levels?

DR. MITCHELL: I do not have them on here, no. Now, this is the analysis of the neat samples. Now, you notice that in this case the samples that are in blue, we haven't had the same process that we had before or that we had with the urine. The blue should be directed assays because, as you have noticed --we'll do this. We should be able to show that the blue lines up with the holes.

Again, the red means that the test is not available as far as that is the X's, and I'm not sure why the red values are in there. Let's see if I can figure out. Well, it looks like they highlighted that and made the color in it for the numbers. It doesn't mean --the red is the results of directed values.

DR. SAMPLE: It doesn't look like lab H did any screening.

DR. MITCHELL: They did no screening at all.

DR. SAMPLE: That's why it's red rather than blue.

DR. MITCHELL: That's right, okay. Some interesting things that we see in the neat samples is that the SD's are about between 15 and 20 percent, in that range on many of the samples. They're 15 to 20 percent of the means for each of the analytes. I think on the THC it gets a little bit higher, but that's to be expected. Most of the laboratories are able to confirm at the levels that they were given. We have a few empty spaces, as you see here, where they did not end up with a confirmation area. We've got to remember that these values are in nanograms per milliliter of oral fluid, which means that we're dealing at, compared to what we're looking at in hair, they're much higher levels and they're easily obtainable normally through GC/MS.

MR. BLEVINS: Open spaces are negative?

DR. MITCHELL: Open spaces means we didn't get a value.

MR. BLEVINS: Just didn't get a value?

DR. MITCHELL: Yes.

MR. BLEVINS: In previous slides you've said that open spaces are negative.

DR. MITCHELL: That's in screening only, in screening only. That's the absence of a value. Now, there's reasons for the absence of a value. For example, on this one we had one lab that said we had amphetamine in that sample at 2.86 nanograms per mL. I think there was one or two labs that screened it positive for amphetamine.

MR. BLEVINS: On the neat samples, they all screened it positive.

DR. MITCHELL: Yes, they all screened it positive, but this is the only lab that found amphetamine.

MR. BLEVINS: But it wasn't present.

DR. MITCHELL: It wasn't present, right. We did not put any amphetamine into that sample. We don't know where it came from at this point in time. We'll investigate that further.

DR. SAMPLE: Is that human oral fluid or is that artificial oral fluid?

DR. MITCHELL: That's human oral fluid.

DR. SAMPLE: So the assumption is that it's truly negative.

DR. MITCHELL: None of the reference labs found any amphetamine, but we'll have it looked at a little bit closer. We always. do that when we find something unexpected. Again, here with THC we have one lab that found THC in this sample, which was not supposed to have any. We haven't had a chance to investigate that, but we will. We still have plenty of samples to look at. But we've also had some of those types of findings in hair. Unfortunately, in hair we can't tell. We don't have an accurate history. With the oral fluid we do have an accurate history of it.

That was the neat samples which had not been absorbed onto the collection device. 4B is the screening results and I think, if these things will overlap, which they're supposed to, we can see that there were some differences. The bottom is the screening before, in other words the neat samples, and you can see here through here that, like in this area, that there are some that screened positive neat but did not screen positive when they were put onto the collection device. It would appear that we may be losing some material that is not being absorbed from the collection devices, and that's the main thing we needed to get out of that one. This should be reflected on the other tables.

I'm going to skip 5A and look at 5B, which is confirmation on the collection device. The results, still we've got between the directed and the assays and the initial tests, we see that we have got a fairly full table of values, which means the laboratories are able on the two different samples, were able to confirm the material in most of the cases.

Now, let's look at a comparison between analyte.

(Screen)

What we did, I'm only showing a comparison where we had three or more analyses of that particular sample. You can see that with methamphetamine the results are very comparable at the various levels that were included in this sample. With amphetamine, the sample results, very comparable. There doesn't appear to be any problems in getting the material off of the collection devices that were used.

(Screen)

Cocaine, pretty much the same story. They're comparable. We'll look and see about statistical differences. This is benzoylecgonine. Morphine, there appears to be a small effect, there may be a small effect, because the morphine is always lower. We expected it to be going back and forth, but it wasn't. I'm not sure of that.

You see the same thing with 6-acetylmorphine, potentially small effects of the device. Codeine again, all of the absorbed are less, slightly less, the values. PCP you don't see much. They were less, but that appears to be it. Going to THC we would expect it. If there was going to be a problem, it would be here. Hence, we can see that there is quite a significant difference in THC concentrations, the neat versus that that's been absorbed to the devices. Knowing what we know about THC, anything it touches it absorbs to and it's hard to get off. It's just one of those, it's a phenomenon of the compound that we can expect.

DR. VOGL: You said each one of those is based on at least three results.

DR. MITCHELL: That's correct.

DR. VOGL: I heard you say before you showed these charts that some of the devices didn't detect it.

DR. MITCHELL: There were a few of that. What I said was in the screening there were some of the devices that the screening, it reduced the concentration such that you got a negative.

DR. VOGL: In the screening.

DR. MITCHELL: It was in the screening process. But there were a couple, I know of a couple that the lab did not provide us any values once it had been put onto the device. But I haven't done a complete analysis of that yet.

(Screen)

Of course, the orphan child of the system, the sweat patch. We had one lab and one reference lab. All we can look at there is the consistency between the two laboratories. It's very difficult to develop on a single sample what's been analyzed by two different laboratories, to develop much in statistics. But they do appear to agree for the most part, the reference lab and the laboratory. Some of them, we only have one value.

We got some data recently from a reference lab that I don't think was incorporated into this. To answer your question, it doesn't look like it was. But for the most part, it appears to -- let's see. What were the cutoffs again. There was an issue for the sweat.

From a confirmation standpoint with the THC, they appeared to be able to meet the cutoff that they at least established there. Not a lot of data, so there's not a lot I can say about it at this point in time.

For the slide, the anticlimactic slide. Let's try to place things in proper perspective.

Before I put it up there, to give you a little bit of background, the urine program started about 1987, that is the pilot PT program. 1986, Ken says. I have '86 here. You're right. So Ken had a program, a pilot PT program, just as we're doing with these laboratories in hair, sweat, and oral fluid. I went back to Ken's paper and got some standard deviations out of there so that we might be able to compare to what we're seeing today in a pilot PT program. I went back and looked at the standard deviations for the first year of the certified laboratories and also the laboratories in the year 2000. I've got bar graphs for each of analytes.

(Screen)

Green is hair, magenta is the oral fluids. This will be urine in 1986, this is urine in 1988, and this one right here is urine in the year 2000.

If we look at the first three, we can see that in some cases the CV's are better than what we saw with the urine back in that time, and sometimes urine is greater, such as cocaine. We know why that is. It's because back in this time laboratories were not aware or not cognizant of the effect of the conversion of cocaine to benzoylecgonine. They did not get feedback between cycles, as we've done here, for them to be able to compare. We know that that was going to happen.

We can see how the BZE shot up because it's converting. Then go over to morphine. We have similar. 6-AM is not looked at in the urine in 1986. Codeine, for some reason the urine SD's were very high at that point in time. PCP's, the urine is very low. THC wasn't in the urine system. THCA's, we can see here for hair very good, and for the urines. This is very comparable. The process in this is to show that in the private PT program you're going to have large standard deviations because you're going to have labs of varying capabilities, and that's what we have. But once we go to a certification process, only laboratories that meet the requirements are going to be able to get in and to stay.

We see that from the 1988. You can see now the SD's, the coefficient of variations are down, which is a measure --are down to 10 to 15 percent for the urine, except in the case of THCA. The reason for THCA was that in 1986-87 --the NIST standard came out around '88, '89, and that was the first standard for THCA that could be used throughout this laboratory program with this difficult analyte to provide some means of comparison.

We can see from today, though, that the average standard, average CV's, are less than 10 percent except with THC and then it's over by 13 percent in the urine system. So over time they've developed their procedures, they've fine-tuned them to the point that there's very little variation in the values.

MR. THISTLE: We've seen some of this past data come out in marketing materials. Just maybe a caution from you that some of the labs participating in these studies don't necessarily do the type of testing that they're doing, they don't necessarily do it commercially. They're seeing what they can do. They're checking out their capabilities. It is inappropriate to use this data to draw the types of conclusions that you would put in marketing materials about what matrices are capable of doing and not doing.

DR. MITCHELL: I totally agree with you at this point in time. All it shows is the general state of the industry for those people who were in this program. That's all it's showing. We're not picking out individuals. I've tried to be very cautious in what I've said so that I don't draw too many conclusions, but to point to generalities that I see within a particular matrix. I'm not drawing conclusions about a system.

MR. THISTLE: I'm not commenting on you.

DR. MITCHELL: I think that's why I'm cautious, because I don't want to make too much of what I've got.

DR. SAMPLE: Were any of these samples paired samples? Where it's the same sample but with a different number?

DR. MITCHELL: There are some samples which were sent out several times and that you can look at, because in the data that we provide with each one we've had the sample number, and if that sample number is the same that means that it was the same sample that had been sent out over two different time frames. So that can be looked at. I have not done that analysis yet.

I would like everybody to know that I don't do all of this. I have Dale Hart and Andy McDaniel who've spent a lot of hours working on this to help me make this presentation today. It's not just me. They're the ones that have aided me and gone under my direction and gotten this ready for today. I owe them a lot of thanks. A lot of hours went into this.

MR. STEPHENSON: Well, this is the area where we say, all right, we've gotten to a point where we've looked at PT's. We have draft 3 of the guidelines that are out there. As Donna had reminded me earlier, you know, this is fine, we can go forward with the final text for procedures, but in fact where we actually implement the program it's going to require two other elements. It's going to require performance in the PT's and it's going to require correct interpretation of results and the ability of the medical review officer community to do that.

DR. BUSH: Actually, I got a lot of input from medical review officers who I recently saw in a training session. Generally, when docs are taking a look at doing drug testing under federal regulations and all of this they want to play by the book, they want to make sure they're affording all the opportunity for persons to discuss reasons why on positive as well as walk the line with what the regulations' time lines, what they have to do, who they have to notify when, paperwork. They want to know all of that stuff.

Needless to say, nice decision trees and algorithms come into play. A lot of docs, after I gave them 90 minutes of alternative matrix drug testing information and things where we're going, history of where we've been, they said to me: You know, we can't wait to see that MRO manual that you write for this. I think that's the next working group we need to pull together here, because we're going to have to take a look at all of these, the specimens that we have and the results that we get, and take a look at interpretation and whether we're looking at alternative medical explanation for presence of drugs in the oral fluid or the urine or the hair or the sweat patch, what are we looking for here and what kind of time lines in the pharmacokinetic pattern play into this.

I guess this is a call for volunteers to begin with the medical review officer manual. I think it's time. We've got enough technical going. We're accumulating a lot of literature. We've

got a lot of industry partners who have experience with their technology and we're going to need some interpretation stuff written.

MR. LoDICO: I think we're at the crossroads where we're going over, deciding that this is what it will look like, and then write the manual and the guidelines and the interpretation.

DR. BUSH: You did have that as one of your slides, and in fact I heard that from the group I spoke to recently: MRO training for the current program. They're anxious to see what we all can come up with to help them do the best job in interpreting the drug test results, knowing the limitations. It's funny because one of the quotes that I use a lot in training sessions that I give --I always try to bring a little humor to things and put it into perspective. I always say one of the great philosophers of our time, Clint Eastwood, in one of his Dirty Harry movies said: "A man's got to know his limitations." It's a matter of knowing the limitations every time we take on a drug test, take on an analytical event in the laboratory. What are the limitations of what we have here, the goods, the bads, and the uglies.

If you want to step up to the plate today, fine. All takers are welcome. Walt's email address is wvogl@samhsa.gov. Mine is dbush@samhsa.gov. Charlie's is clodico@samhsa.gov. Help us with this. It's time.

MR. STEPHENSON: I'd like to make sure that we do a very deliberate outreach to the organized MRO groups and the entities that provide bundled services and have databases that they use to track the systems, because a part of what I hope to have come out of this is not just a working group at the front edge of correct interpretation, but how to keep this a living process, that we're able to revisit and modify as time goes on based on experience.

This is going the be important to us, not only in testing for drugs of abuse, but also in specimen validity testing and also looking at what happens as new drugs, maybe over the counter medications, other kinds of things, come into the marketplace that can help muddy the picture for us periodically. These are things that are very real and we have demonstrated over the last decade that we're able to do this as a living, breathing program that's able to change and modify. We are always going to be behind the power curve because we aren't the ones introducing the illegal drugs into the marketplace. We are not the ones that are introducing the patterns of behavior for adulterants or substitution methodologies. We have to always look at correcting the results and learning from our experiences. I see the MRO group as being a very critical group to help us do this in a very real and ongoing way. You have been in the past and I think you'll continue to be so in the future. Please, think about what you can provide and how you can help us.

Agenda Item: Public Comments

MR. MORRIS (ALPA): I'm a Delta Captain and Executive Vice President of ALPA. ALPA (Airline Pilots Association) still has substantial and serious concerns about drug testing in general and validity testing specifically. Just to refresh some memories, last September we were successful in the defense of a pilot who had been accused of substituting his urine sample. The individual returned from a run to New York --it's like a ten-hour flight --a 145 pound individual in his mid-forties. Now, just prior to the flight he had one serving of non-fat cottage cheese and

then during the flight he didn't eat a thing, but he did drink approximately three liters of water. This was not typical pilot behavior, let me tell you. But he's a very health-conscious individual.

He was tested and was accused of a substituted sample. Now, we were able to defend the pilot because not of any procedure that is in the existing drug testing rules, but rather because his certificate was removed or revoked by the FAA. When that happens for whatever reason it is, whether it's pilot certificate or a medical certificate, there is a procedure to have a National Transportation Safety Board review.

An administrative law judge took this case and if it had gone past that case we would have had a chance to take this case before the entire NTSB. The end result was the FAA on the courthouse steps withdrew their case with prejudice based upon the overwhelming information that we were to present.

As a net result of that, there was an inspection that was ordered of all the national laboratories, a majority of which failed that inspection, and approximately 300 test results for workers nationwide were cancelled.

Now, we think this is interesting for a number of different reasons, and I think you should, too. The original cases that kind of brought this to the forefront happened at Delta. It just happened to be the circumstance that we had a few cases, and they started with the flight attendant cases and I became aware of it. We did some publicity of it and we started to work through the issue. Of the six known Delta cases, only one of them received a test cancellation within that group of 300. That's very interesting. We think there's some reasons because when the inspection of the labs was done and the resulting cancellations they looked only very narrowly at the landmark case, at the pilot case. They looked at the ability for a truncation of results and they looked at LLL readings on the specific gravity test.

But they didn't look at the larger issue of the accuracy of the assay. If they had done that, without doubt there was very serious problems at a particular lab that we were using, a prominent lab. But even today, the accuracy of the assay could cause many false results.

So we think that, based upon the fact that, of the six known cases, only having one cancelled, not even including the landmark case --his was cancelled based upon the findings of the court --that potentially there are thousands of cases out there that should have had review, and we continue to pursue that particular issue.

Now, where do we stand today? As some of you may know, ALPA has filed a petition to review in the Ninth Circuit Court of Appeals on the DOT testing. That presently is being held in abeyance through mutual consent until such time as HHS publishes the NPRM on the revised validity testing rules. We think that will make the issue more ripe. We're hopeful that some corrective action is taken in those rules.

I want to make it clear that ALPA's position and labor's position, if I can speak for the broader group, is not to terminate drug testing or to terminate validity testing. What we are trying to achieve is the insertion of legitimate due process into the rules. Now, we will acknowledge that the new DOT rules added on the surface some important "additions to worker protection. Access to the split sample and some review by the MRO on the surface are some additions. However, we think in practice they're very superficial. What we want to see is the ability for accused individuals --and there are going to be very few, but whereas this testing presently, as has been said twice today, is voluntary, unfortunately the terminations that are happening are totally involuntary, and those individuals are owed all the aspects of due process. So presently our methodology has been through the public comment, through media interest. As you know,

the Wall Street Journal and the New York Times have followed this story, and in fact we have national network television that is preparing to talk about it, too.

We can go through that process and we can go through the court process, but we think that's terribly inefficient. What we would rather do is sit down and talk through it and see if we can come up with those sort of protections that satisfy the interests of our constituency and join together in making a better program.

Thank you for your time.

MR. STEPHENSON: Are there any other comments from the public? (No response.)

The open session of the DTAB meeting adjourned at 11:37 a.m.